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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0170]

Abbott Laboratories' Sarafloxacin for Poultry; Withdrawal of Approval of NADAs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) sponsored by Abbott Laboratories. The NADAs provide for use of sarafloxacin to treat poultry. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations by removing the portions reflecting approval of these NADAs.

DATES: Withdrawal of approval is effective April 30, 2001.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, North Chicago, IL 60064, is sponsor of the following NADAs: (1) NADA 141–017 SaraFlox® (sarafloxacin hydrochloride) WSP, a water-soluble powder used in the drinking water of broiler chickens and growing turkeys for control of mortality associated with *Escherichia coli* in (21 CFR 520.2095); and (2) NADA 141–018 SaraFlox® (sarafloxacin hydrochloride) Injection, an injectable solution used in 18-day embryonated broiler eggs and day-old broiler chickens for control of early chick mortality associated with *E. coli* (21 CFR 522.2095).

The sponsor was informed by FDA that, on the basis of new data and information before it, there is a question of human food safety, due to the use of fluoroquinolones such as sarafloxacin

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in poultry. After being informed by FDA of this question, Abbott Laboratories requested voluntary withdrawal of approval of NADAs 141–017 and 141–018. By doing so, the firm waived its opportunity for hearing.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADAs 141–017 and 141–018, and all supplements and amendments thereto is hereby withdrawn effective April 30, 2001. Any new animal drug product that is not the subject of an approved application is subject to regulatory action at any time.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.

Dated: 4/17/01
April 17, 2001.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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